

Discussion Draft for 7-26-04 Advisory Meeting

Please Note: This draft is provided solely for the purposes of discussion at the July 26, 2004 advisory meeting on controlling employee exposure to airborne infectious diseases, and is not a rulemaking proposal.

Airborne Infectious Diseases

(a) Definitions

Acid-fast bacilli (AFB) means bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast organisms are mycobacteria.

Accredited laboratory means a laboratory that has participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories.

Airborne Infection Isolation room or area means a room, area, booth, tent, or other enclosure that are maintained at negative pressure to adjacent areas in order to control the spread of aerosolized **M. tuberculosis** and other significant infectious pathogens, and that meets the requirements of Title 24, Part 4, Chapter 4, Part III, Section 414 et seq for Isolation Rooms, or the requirements stated in subsection (d) of this standard

Airborne Infection Isolation means infection control procedures that are designed to reduce the risk of transmission of infectious agents through dissemination of either airborne droplet nuclei (small-particle residue [5 µm or smaller in size] of evaporated droplets that may remain suspended in the air for long periods of time) or dust particles containing the infectious agent. Microorganisms carried in this manner can be dispersed widely by air currents and may become inhaled by or deposited on a susceptible host within the same room or over a longer distance from the source patient, depending on environmental factors; therefore, special air handling and ventilation are required to prevent airborne transmission. Airborne Infection Isolation procedures apply to patients known or suspected to be infected with epidemiologically important pathogens that can be transmitted by the airborne route.

Anergy means the inability of a person to react to skin test antigens (even if the person is infected with the organisms tested) because of immunosuppression.

BCG (Bacille Calmette-Guerin) vaccine is a tuberculosis vaccine.

CDC means the United States Centers for Disease Control and Prevention.

CDHS means the California Department of Health Services.

Clinical laboratory is a laboratory or area of a facility that conducts routine and repetitive operations for the diagnosis of TB and other airborne infectious diseases, such

as preparing acid-fast smears and culturing sputa or other clinical specimens for identification, typing or susceptibility testing.

Confirmed infectious state is a disease state that has been diagnosed by positive identification of **M. tuberculosis** or other significant infectious pathogen from body fluid or tissue through positive culture, positive gene probe, or positive polymerase chain reaction (PCR). The disease state must be capable of being transmitted to another individual (e.g., pulmonary or laryngeal TB or extrapulmonary TB where the infected tissue is exposed and could generate droplet nuclei).

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Droplet Precautions means infection control procedures designed to reduce the risk of transmission of infectious agents through contact of the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets (larger than 5 µm in size) containing microorganisms generated from a person who has a clinical disease or who is a carrier of the microorganism. Droplets are generated from the source person primarily during coughing, sneezing, or talking and during the performance of certain procedures such as suctioning and bronchoscopy. Transmission via large-particle droplets requires close contact between source and recipient persons, because droplets do not remain suspended in the air and generally travel only short distances, usually 3 ft or less, through the air. Because droplets do not remain suspended in the air, special air handling and ventilation are not required to prevent droplet transmission. Droplet Precautions apply to any patient known or suspected to be infected with epidemiologically important pathogens that can be transmitted by infectious droplets.

Exposure incident means an event in which an employee has been exposed to an individual with confirmed infectious TB or other confirmed significant airborne disease or to air containing aerosolized **M. tuberculosis** or significant infectious pathogen without the benefit of applicable exposure control measures required by this section.

First receiver means an organization that is expected to receive victims from the site of an emergency response as defined in 5192. A first receiver is located away from the site of a hazardous substance release.

High hazard procedures means procedures performed on an individual with suspected or confirmed infectious tuberculosis or other confirmed significant airborne disease in which the potential for being exposed to **M. tuberculosis** or other significant infectious pathogens is increased due to the reasonably anticipated generation of aerosolized pathogens. Such procedures include, but are not limited to, sputum induction, bronchoscopy, endotracheal intubation or suctioning, aerosolized administration of pentamidine or other medications, and pulmonary function testing. They also include autopsy, clinical, surgical and laboratory procedures that may aerosolize significant infectious pathogens.

Medical Removal Protection means the maintenance of earnings, seniority and other benefits specified in paragraph (g)(5) of this section for an employee who has confirmed or suspected infectious TB or other SID, or is unable to wear a respirator.

M. tuberculosis means **Mycobacterium tuberculosis**, the scientific name of the bacillus that causes tuberculosis.

Negative pressure means the relative air pressure difference between two areas. A room that is under negative pressure has lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas.

Occupational exposure means reasonably anticipated contact, that results from the performance of an employee's duties, with an individual with suspected or confirmed infectious TB or other significant airborne disease or air that may contain aerosolized **M. tuberculosis** or other significant infectious pathogen.

Physician or other licensed health care professional means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the health care services required by subsection (g) of this section.

Research laboratory is a laboratory that propagates and manipulates cultures of **M. tuberculosis** or other significant infectious pathogen in large volumes or high concentrations that are in excess of those used for identification and typing activities common to clinical laboratories.

Respirator means a device worn by an individual and intended to provide the wearer with respiratory protection against inhalation of airborne contaminants.

Significant infectious pathogen means a pathogen identified by the CDC or the CDHS as requiring airborne or droplet precautions, including **M. tuberculosis**.

Significant infectious disease means a disease identified by the CDC or the CDHS as requiring airborne infection isolation, including tuberculosis, or droplet precautions.

Suspected infectious state means a potential disease state in which an individual is known, or with reasonable diligence should be known, by the employer to have one or more of the following conditions, unless the individual's condition has been medically determined to result from a cause other than TB or other significant infectious disease:

- (1) To be infected with **M. tuberculosis** and to have the signs or symptoms of TB;
- (2) To have a positive acid-fast bacilli (AFB) smear; or
- (3) To have a persistent cough lasting 3 or more weeks and two or more symptoms of active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia). An individual

with suspected infectious TB has neither confirmed infectious TB nor has he or she been medically determined to be noninfectious.

(4) To meet the criteria described by the Centers for Disease Control or the California Department of Health services of a suspect case for a significant infectious disease.

TB Conversion means a change in tuberculin skin test results from negative to positive, based upon current Centers for Disease Control and Prevention (CDC) guidelines.

Tuberculosis (TB) means a disease caused by **M. tuberculosis**.

Tuberculosis infection means a condition in which living **M. tuberculosis** bacilli are present in the body without producing clinically active disease. Although the infected individual has a positive tuberculin skin test reaction, he or she may have no symptoms related to the infection and may not be capable of transmitting the disease.

Tuberculosis disease is a condition in which living **M. tuberculosis** bacilli are present in the body, producing clinical illness. The individual may or may not be infectious.

Tuberculin skin test means a method used to evaluate the likelihood that a person is infected with **M. tuberculosis**. The method utilizes an intradermal injection of tuberculin antigen with subsequent measurement of the reaction induration. It is also referred to as a PPD skin test.

Two-step testing is a baseline skin testing procedure used to identify a boosted skin test reaction from that of a new infection. The procedure involves placing a second skin test 1 to 3 weeks after an initial negative test. A positive reaction on the second test indicates a boosted reaction.

(b) Scope. This section applies to occupational exposure to tuberculosis (TB) and other significant infectious disease or pathogens occurring:

- (1) In hospitals;
- (2) In emergency response organizations, including paramedics and emergency medical transport, first receivers, and fire and police personnel.
- (3) In long term care facilities for the elderly;
- (4) In correctional facilities and other facilities that house inmates or detainees;
- (5) In hospices;
- (6) In shelters for the homeless;
- (7) In facilities that offer treatment for drug abuse;

- (8) In facilities where high-hazard procedures (as defined by this section) are performed;
- (9) In laboratories that handle specimens that may contain **M. tuberculosis** or other significant infectious pathogens, or process or maintain the resulting cultures, or perform related activity that may result in the aerosolization of **M. tuberculosis** or other significant infectious pathogens;

Note to subsection (a)(2): Emergency response personnel at the site of a hazardous substance release, or who may be reasonably anticipated to be exposed to unknown or IDLH quantities of hazardous substances, as defined in section 5192, must also be protected as required by section 5192(q).

Note to subsection (a)(9): Occupational exposure incurred in any of the work settings listed in paragraphs (a)(1) through (a)(8) of this section by temporary or contract employees or by personnel who service or repair air systems or equipment or who renovate, repair, or maintain areas of buildings that may reasonably be anticipated to contain aerosolized **M. tuberculosis** or other significant infectious pathogens is covered by this section.

(c) Infectious Disease Exposure Control Plan

(1) Written plan.

(A) Each employer having an employee(s) with occupational exposure as defined by subsection (b) of this section shall establish, implement and maintain an effective Infectious Disease Exposure Control Plan (Plan) which is designed to eliminate or minimize employee exposure.

(B) The Plan shall be in writing and shall contain at least the following elements:

1. The exposure determination required by subsection (c)(2);
2. The schedule and method of implementation for each of the applicable subsections: engineering controls, work practice controls, personal protective equipment, respiratory protection, vaccination, medical surveillance, training, hazard communications, and record-keeping (reference to appropriate subsection). Specific engineering, work practice, personal protective and respiratory protective control measures shall be listed for each task in which occupational exposure occurs;
3. The procedure for the evaluation of circumstances surrounding exposure incidents;
4. An effective procedure for identifying currently available engineering controls, and selecting such controls, where appropriate, for the procedures performed by employees in their respective work areas or departments;

5. An effective procedure for obtaining the active involvement of employees in reviewing and updating the exposure control plan with respect to the procedures performed by employees in their respective work areas or departments.

(C) Each employer shall ensure that a copy of the Plan is accessible to employees in accordance with Section 3204(e).

(D) The Plan shall be reviewed and updated at least annually and whenever necessary as follows:

1. When the CDC or the CDHS announces that additional pathogen(s) require droplet precautions or airborne infection isolation, revises case definitions for a significant infectious disease, or revises recommendations for control measures for significant infectious diseases;
2. To reflect new or modified tasks and procedures which affect occupational exposure;
3. To reflect changes in technology that eliminate or reduce exposure to M. Tuberculosis and other significant infectious pathogens;
4. To include new or revised employee positions with occupational exposure;
5. To review and evaluate the exposure incidents which occurred since the previous update; and
6. To review and respond to information indicating that the Plan is deficient in any area.

(E) Employees responsible for direct patient care. In addition to complying with subsections (c)(1)(B)5., the employer shall solicit input from non-managerial employees responsible for direct patient care in the identification, evaluation, and selection of effective engineering and work practice controls, and shall document the solicitation in the Plan.

(F) The Plan shall be made available to the Chief or NIOSH or their respective designee upon request for examination and copying.

(2) Exposure Determination.

(A) Each employer who has an employee(s) with occupational exposure as defined by subsection (a) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

1. A list of all job classifications in which all employees in those job classifications have occupational exposure;
2. A list of job classifications in which some employees have occupational exposure; and

3. A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of subsection (c)(2)(A)2. of this standard

4. A list of all high risk procedures performed by employees.

(B) This exposure determination shall be made without regard to the use of personal protective equipment.

(d) Work Practices and Engineering Controls and Personal Protective Equipment

(1) Work practices and engineering controls shall be used to eliminate or minimize employee exposures to significant infectious diseases (SID).

(2) The work practices in the Infectious Diseases Exposure Control Plan shall be developed to prevent or minimize employee exposures to droplet and contact transmission of significant infectious pathogens (SIP). These work practices shall include but not be limited to appropriate handwashing and gloving procedures; the use of respiratory, eye and face protection; the use of gowns and other protective apparel; and adequate disinfection of contaminated surfaces, articles and linens.

(3) Individuals with suspected or confirmed infectious TB or other significant infectious disease that requires airborne infection isolation, shall be identified and except in settings where home health care or home-based hospice care is being provided, shall be:

(A) Masked or segregated in such a manner that contact with employees who are not wearing respiratory protection is eliminated or minimized until transfer or placement in an Airborne Infection Isolation (AII) room or area can be accomplished; and

(B) Placed in an AII room or area or transferred to a facility with AII rooms or areas within 5 hours from the time of identification, or temporarily placed in AII within 5 hours until placement or transfer can be accomplished as soon as possible thereafter.

(4) High-hazard procedures for shall be conducted in an AII room or area.

(5) Engineering controls shall be used in facilities that admit or provide medical services or AII to individuals with suspected or confirmed infectious TB or other SIP that requires airborne infection isolation, except in settings where home health care or home-based hospice care is being provided. Facilities constructed pursuant to Title 24, Part 4, Chapter 4, Section 417 et seq, and which are maintained to meet those requirements, shall be considered to be in compliance with this subsection.

(A) Negative pressure shall be maintained in AII isolation rooms or areas. The ventilation rate shall be 12 or more air changes per hour.

(B) Negative pressure shall be qualitatively demonstrated (e.g., by smoke trails) daily while a room or area is in use for TB or SAP isolation (see appendix).

(C) Engineering controls shall be maintained, and inspected and performance monitored for filter loading and leakage every 6 months, whenever filters are changed, and more often if necessary to maintain effectiveness (see appendix).

(D) Air from AII isolation rooms or areas shall be exhausted directly outside, away from intake vents, employees, and the general public. Air that cannot be exhausted in such a manner or must be recirculated must pass through HEPA filters before discharge or recirculation.

(E) Ducts carrying air that may reasonably be anticipated to contain aerosolized **M. tuberculosis** or other SIPs that require airborne infection isolation shall be maintained under negative pressure for their entire length before in-duct HEPA filtration or until the ducts exit the building for discharge.

(F) Doors and windows of AII rooms or areas shall be kept closed while in use for airborne isolation, except when doors are opened for entering or exiting and when windows are part of the ventilation system being used to achieve negative pressure.

(G) When an AII room or area is vacated by an individual with suspected or confirmed infectious TB or other SIP requiring airborne infection isolation, the room or area shall be ventilated according to current CDC recommendations for a removal efficiency of 99.9 % before permitting employees to enter without respiratory protection.

(6) The employer shall provide information about the infectious disease hazard to any contractor who provides temporary or contract employees who may incur occupational exposure so that the contractor can institute precautions to protect his or her employees.

(7) Response to offsite emergency situations involving the release of pathogenic organisms shall be conducted in accordance with Section 5192, Hazardous Waste Operations and Emergency Response.

(8) Employers who will provide medical care for mass disease outbreaks or exposures to pathogenic organisms shall establish work practices and procedures, including the selection of appropriate personal protective equipment and respiratory protective equipment, for such events. Employees designated to provide care under these circumstances shall be trained in these practices and procedures.

(e) Laboratories (to be added later)

(f) Respiratory Protection

(1) Employers shall provide a respirator to each employee who:

- (A) Enters an AII room or area in use for airborne isolation;
- (B) Is present during the performance of procedures or services for an individual with suspected or confirmed infectious TB or SIP who is not masked;
- (C) Transports an individual with suspected or confirmed infectious TB or SIP in an enclosed vehicle (e.g., ambulance, helicopter) or who transports an individual with suspected or confirmed infectious TB or SIP within the facility when that individual is not masked;
- (D) Repairs, replaces, or maintains air systems or equipment that may reasonably be anticipated to contain aerosolized **M. tuberculosis** or other SIP;
- (E) Is working in an area where an unmasked individual with suspected or confirmed infectious TB or other SIP has been segregated or otherwise confined (e.g., while awaiting transfer); or
- (F) Is working in a residence where an individual with suspected or confirmed infectious TB or other SIP is known to be present.

(2) The employer shall provide the respirator at no cost to the employee and shall assure that the employee uses the respirator in accordance with the requirements of this section and section 5144. **[[Issue: Adding to or subtracting from requirements of section 5144 to tailor requirements more specifically to airborne infectious disease.]]**

(3) The employer shall assure that the employee dons the respirator before entering any of the work settings or performing any of the tasks set forth in subsection (f)(1) of this section and uses it until leaving the work setting or completing the task, regardless of other control measures in place.

(4) Each employer who has any employee whose occupational exposure is based on entering any of the work settings or performing any of the tasks described in paragraph (f)(1) of this section shall establish and implement a written respiratory protection program that meets the requirements of Section 5144. Respirators shall be selected and used in accordance with CDC and CDHS guidelines.

(g) Medical Surveillance

(1) Each employer who has any employee with occupational exposure shall provide the employee with medical surveillance for tuberculosis and other SIDS as recommended by the CDC and/or the CDHS. When an employer is also acting as the evaluating health care professional, the employer shall advise an employee following an exposure incident that the employee may refuse to consent to post-exposure evaluation and follow-up from the employer-healthcare professional. When consent is refused, the employer shall make immediately available to exposed employees a confidential medical evaluation and follow-up from a healthcare professional other than the exposed employee's employer.

(2) Medical surveillance provisions, including vaccinations, examinations, evaluations, determinations, procedures, and medical management and follow-up, shall be:

(A) Provided at no cost to the employee;

(B) Provided at a reasonable time and place for the employee and during the employee's working hours;

(C) Performed by or under the supervision of a physician or other licensed health care professional, as appropriate; and

(D) Provided according to recommendations of CDC and/or CDHS current at the time these evaluations and procedures take place;

(E) Laboratory tests shall be conducted by an accredited laboratory.

(3) The employer shall make available to all employees with occupational exposure all vaccinations and immunizations recommended by the CDC and/or the CDHS to protect employees from significant infectious diseases.

(A) Recommended vaccinations shall be made available after the employee has received the training required in subsection (h) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the recommended vaccination(s), antibody testing has revealed that the employee is immune, or the vaccine(s) is contraindicated for medical reasons.

(B) The employer shall make additional vaccination(s) available to employees within ten days of the issuance of new CDC or CDHS recommendations.

Exception: Where the employer can not implement these recommendations because of the lack of availability of vaccine, the employer shall document efforts made to obtain the vaccination in a timely manner and inform employees of the status of the vaccine availability.

(C) The employer shall not make participation in a prescreening program a prerequisite for receiving a vaccine.

(D) If the employee initially declines a vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make the vaccination available within ten days of that request.

(E) The employer shall assure that employees who decline to accept a recommended vaccination offered by the employer sign the statement in Appendix ____.

(4) **Exposure Incidents.**

(A) The employer shall assure that when the physician or other licensed health care professional, as appropriate, determines that an employee has suspected or confirmed infectious TB or other SID, the physician or other licensed health care professional, as appropriate, shall notify the employer and the employee as soon as feasible.

(B) When the employer first identifies an individual with confirmed infectious TB or other SID, the employer shall notify each employee who has had an exposure incident involving that individual of his or her exposure; and

(C) When an exposure incident results in a TB skin test conversion or other test conversion, the employer shall assure that a determination is made of the drug susceptibility of the **M. tuberculosis** isolate from the source, unless the employer can demonstrate that such a determination is not feasible.

(D) When an exposure incident or a TB skin test conversion or other test conversion occurs, the employer shall investigate and document the circumstances surrounding the exposure incident or conversion (**e.g.** failure of engineering controls or work practices and events leading to the exposure incident) to determine if changes can be instituted to prevent similar occurrences in the future.

(5) Medical Removal

(A) Each employee with suspected or confirmed infectious TB or other SID shall be removed from the workplace until determined to be noninfectious.

(6) [[Issue: Medical Removal Protection benefits?]]

(7) Information Provided to Physician or Other Licensed Health Care

Professionals. (A) Each employer shall assure that all physicians or other licensed health care professionals responsible for making determinations and performing procedures as part of the medical surveillance program are provided a copy of this regulation, applicable CDC and CDHS guidelines, and, for those employees required to wear respirators under this section, information regarding the type of respiratory protection used, a description of the work effort required, any special environmental conditions (**e.g.**, heat, confined space entry), additional requirements for protective clothing and equipment, and the duration and frequency of usage of the respirator.

(B) Each employer shall assure that the physician or other licensed health care professional, as appropriate, who evaluates an employee after an exposure incident is provided the following information:

1. A description of the exposed employee's duties as they relate to the exposure incident;
2. Circumstances under which the exposure incident occurred;

3. Any diagnostic test results, including drug susceptibility pattern or other information relating to the source of exposure which could assist in the medical management of the employee; and

4. All of the employee's medical records relevant to the management of the employee, including tuberculin skin testing and other relevant testing for SID infections.

(8) Written Opinion.

(A) Each employer shall obtain and provide the employee with a copy of the written opinion of the physician or other licensed health care professional, as appropriate, within 15 days of the completion of all medical evaluations required by this section.

(B) The written opinion shall be limited to the following information:

1. The employee's TB skin test status or applicable SID test status;
2. The employee's infectivity status;
3. A statement that the employee has been informed of the results of the medical evaluation;
4. A statement that the employee has been told about any medical conditions resulting from exposure to TB or other SID that require further evaluation or treatment;
5. Recommendations for medical removal or work restrictions and the physician's or other licensed health care professional's opinion regarding the employee's ability to wear a respirator.

(C) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(h) Communication of hazards and training

(i) Record-keeping